**PCT** WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 15/00 — A1

(11) International Publication Number: WO 95/22365

(43) International Publication Date: 24 August 1995 (24.08.95)

(21) International Application Number: PCT/SE95/00157

(22) International Filing Date: 15 February 1995 (15.02.95)

(30) Priority Data:
9400570-9 21 February 1994 (21.02.94) SE

(71) Applicant *(for all designated States except US)*: ASTRA AKTIEBOLAG [SE/SE]; S-151 85 Södertälje (SE).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: MARNFELDT, Nils, Göran [SE/SE]; Emil Hanssons väg 17, S-270 35 Blentarp (SE). WALDECK, Johan, Mats, Bertil [SE/SE]; Östanbäcksvägen 69, S-247 33 Söndra Sandby (SE).

(74) Common Representative: ASTRA AKTIEBOLAG; Patent Dept., S-151 85 Södertälje (SE).

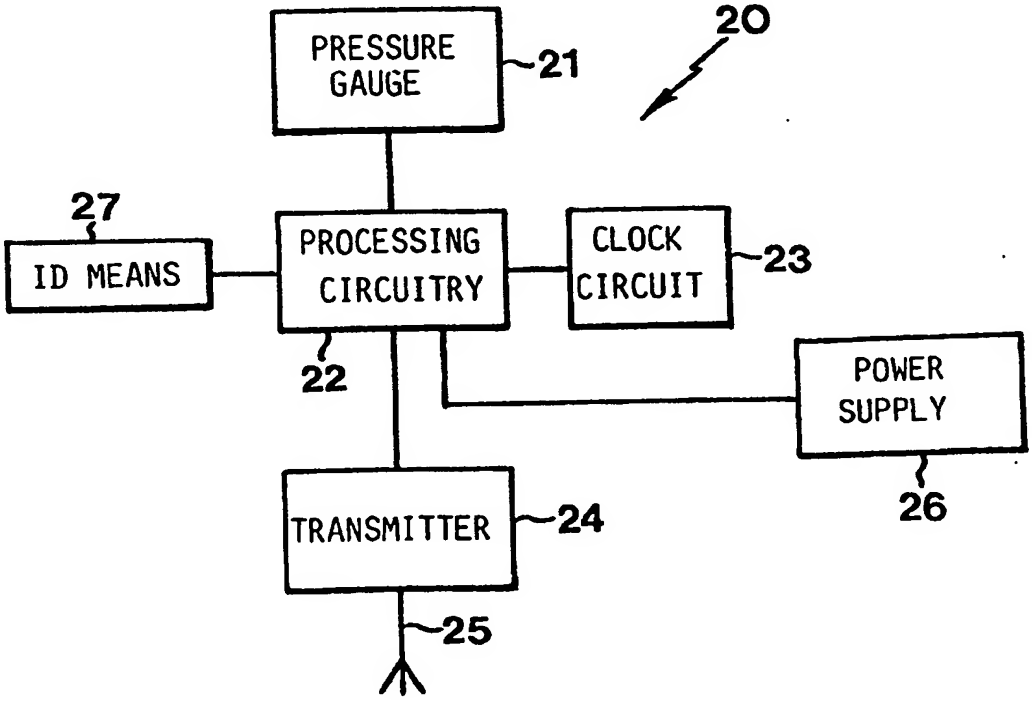
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ, UG).

**Published**
*With international search report.*
*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: INHALATION DEVICE WITH ELECTRONICALLY READABLE IDENTIFICATION MEANS

(57) Abstract

An inhalation device comprises at least one inhaler for dispensing a dose of a drug to a user inhaling through the inhaler. The inhaler, which contains a supply of drug, has means (21-23) for detecting the dispensation of a dose and means (21-23; 38) for measuring a specific feature of the disease being treated with the drug, e.g. the inhalation air flow of an asthmatic. A processing unit (30), which is integrated in the inhaler or provided as a separate unit, has storage means (34) for storing the specific feature from a plurality of measurements as well as the time of each detected dispensation of a dose. To improve the reliability of information recorded in the processing device (30), the inhalation device further comprises electronically readable identification means (27), which are arranged inseparably from the supply of drug and which contain information enabling identification of at least the kind of drug in the supply and the size of the dose dispensed when a user inhales through the inhaler, and means for delivering said information to the processing unit.



*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | |
|---|---|---|---|---|---|
| **AT** | Austria | **GB** | United Kingdom | **MR** | Mauritania |
| **AU** | Australia | **GE** | Georgia | **MW** | Malawi |
| **BB** | Barbados | **GN** | Guinea | **NE** | Niger |
| **BE** | Belgium | **GR** | Greece | **NL** | Netherlands |
| **BF** | Burkina Faso | **HU** | Hungary | **NO** | Norway |
| **BG** | Bulgaria | **IE** | Ireland | **NZ** | New Zealand |
| **BJ** | Benin | **IT** | Italy | **PL** | Poland |
| **BR** | Brazil | **JP** | Japan | **PT** | Portugal |
| **BY** | Belarus | **KE** | Kenya | **RO** | Romania |
| **CA** | Canada | **KG** | Kyrgystan | **RU** | Russian Federation |
| **CF** | Central African Republic | **KP** | Democratic People's Republic of Korea | **SD** | Sudan |
| **CG** | Congo | | | **SE** | Sweden |
| **CH** | Switzerland | **KR** | Republic of Korea | **SI** | Slovenia |
| **CI** | Côte d'Ivoire | **KZ** | Kazakhstan | **SK** | Slovakia |
| **CM** | Cameroon | **LI** | Liechtenstein | **SN** | Senegal |
| **CN** | China | **LK** | Sri Lanka | **TD** | Chad |
| **CS** | Czechoslovakia | **LU** | Luxembourg | **TG** | Togo |
| **CZ** | Czech Republic | **LV** | Latvia | **TJ** | Tajikistan |
| **DE** | Germany | **MC** | Monaco | **TT** | Trinidad and Tobago |
| **DK** | Denmark | **MD** | Republic of Moldova | **UA** | Ukraine |
| **ES** | Spain | **MG** | Madagascar | **US** | United States of America |
| **FI** | Finland | **ML** | Mali | **UZ** | Uzbekistan |
| **FR** | France | **MN** | Mongolia | **VN** | Viet Nam |
| **GA** | Gabon | | | | |

# Inhalation device with electronically readable identification means

The present invention relates to an inhalation device comprising at least one inhaler for dispensing a dose of a drug to a user inhaling through the inhaler, which contains a supply of the drug and which has means for detecting the dispensation of a dose; means for measuring a specific feature of the disease being treated with the drug; and a processing unit having storage means for storing this specific feature from a plurality of measurements as well as the time of each detected dispensation of a dose. The present invention also relates to an inhaler.

Many people who suffer from chronic diseases depend on regular intake of one or more drugs for their health. For example, asthmatics normally take a daily dose of an anti-inflammatory drug to prevent attacks of asthma. It is of great importance that these patients closely follow their prescribed medication programme. If an asthmatic forgets to take his anti-inflammatory drug, his state of health may change for the worse and he may suffer from attacks of asthma. To compensate for drug not taken, it may be necessary to temporarily change the dose of the drug or change drugs. There are also other occasions when a change of dose or of drugs is necessary. For instance, when suffering an attack of asthma, the asthmatic will need a different drug which expands the respiratory passages to mitigate the acute problems. Furthermore, asthma may change slowly over time, necessitating a change of medication programme.

Whenever the condition of an asthmatic becomes worse, it is important to change the medication programme as early as possible to counteract health deterioration. The earlier the counter-measures are taken, the quicker will the troubles of the patient be alleviated and the less is the risk of serious attacks of asthma or lasting deterioration of the patient's condition.

Unfortunately, health deterioration is not always noticed by the patient, or, if noticed, is not always acted on in a proper way or as quickly as desirable. When deciding how to treat deterioration of health in a patient suffering from a chronic disease, it is vital to know if the patient has complied with his medication programme. More particularly, the doctor need to know if the deterioration has occurred despite normal medication or is due to imperfect medication. However, the patient may have difficulties in remembering when he took his drug or may be ashamed of telling his doctor that he forgot to take it.

In clinical trials, patients are asked to fill in a patient's diary each time a dose of drug is taken. However, it is known that the diary is often completed in an incorrect way.

EP 387 222 discloses an inhaler comprising an electronic unit for recording the time each dose is dispensed from the inhaler. A detector, e.g. a microphone, detects the inhalation air flow and the availability of a dose. By determining the amplitude of the signal from the microphone within a narrow frequency band one or more times during the inhalation, an electronical unit decides whether the inhalation is a valid inhalation or not. The time of a valid inhalation is recorded in a memory in the inhaler. When the patient sees his doctor next time, the doctor may open the inhaler and read the content of the memory by special reading equipment. The doctor may then decide if the medication programme has been complied with and, after examining the patient, may decide on a change of medication programme.

However, the inhaler according to EP 387 222 does not solve the problem of making the patient act at an early stage on any health deterioration that may occur.

WO 92/15353 discloses an inhalation device for administering an aerosolised drug to a patient. The inhalation device comprises a cannister containing the drug to be aerosolised, a flow sensor for measuring inspiratory and

expiratory flow, and control circuits for controlling the operation of the device and recording data about the drug administration. Furthermore, the control circuits are adapted to monitor the pulmonary function of the patient with the aid of measured flow data. By comparing the measured pulmonary function with one or more previous measures, the control circuits can detect changes in the patient's condition. When detecting a change in the pulmonary function, the control circuits may modify the medication programme, e.g. by altering the dose administered per inhalation, or prompt the patient to seek medical attention.

Many diseases, for instance asthma, are often treated with more than one kind of drug. A health deterioration of a patient having such a disease can be due to an omitted intake of one or the other of the drugs. To advise the patient correctly in this situation, a doctor or a computer need information about the intakes of all the different drugs used to treat the disease. However, the inhalation device according to WO 92/15353 only records the use of one drug.

Furthermore, it is of vital importance that the recorded information about the drug intakes is correct. If, for instance, an inhalation device records the intake of a first drug, but the patient has actually taken a second drug because he has put the wrong supply of drug in his inhaler, the advice by a doctor or a computer will perhaps not have any effect. There is no guarantee that the intake of drug recorded by the inhalation device according to WO 92/15353 is correct.

These problems of the prior art are solved by an inhalation device, which is mentioned by way of introduction and has the features of claim 1, and by an inhaler which has features of claim 7.

More particularly, electronically readable identification means, which are arranged inseparably from the supply of drug and which comprise information which en-

ables identification of at least the kind of drug in the supply and the size of the dose dispensed when a user inhales through the inhaler, allow a processing unit to record the inhalation of a specific kind of drug correctly on each occasion. The identification means also enable the processing means to keep track of several different drugs used by the patient so that a reliable indication of an action to be taken may be given to the patient.

The above-mentioned information from the identification means is preferably supplied to the processing unit each time the measured specific feature is supplied thereto.

As mentioned above, the electronically readable identification means enhance the reliability of the inhalation device in that the processing unit always records the drug actually inhaled. However, there remains a risk that the supply of drug is empty when the inhalation is being performed. To solve this problem, the inhalation device preferably comprises a counter for counting the number of doses administered. The counter is arranged inseparably from the supply of drug so that the number of dose administrations are counted even though the drug supply is used in another inhaler.

It is important that the electronically readable identification means are inseparable from the supply of drug so that the processing unit always records the drug actually inhaled. In a disposable inhaler with no possibility of a refill or replacement of the supply of drug, the electronic identification means may be arranged anywhere in the inhaler. However, in an inhaler with a supply of drug contained in a replaceable package, the electronic identification means have to be inseparably associated with the package.

The inhalation device may comprise one or more integrated inhalers, each of which may have a replaceable supply of drug or be of disposable type. However, the inhaler or inhalers and the processing unit of the inhala-

tion device may also be physically separate units, which is advantageous if the inhaler is disposable. In the latter case, the inhaler may comprise a transmitter, and the processing unit may comprise a receiver for enabling the transmission of information from the inhaler to the processing unit. The information may be transmitted by radio transmission, induction, IR, ultrasound, cable or in any suitable way.

The electronic identification means preferably comprise a non-volatile storage means, which stores a bit code representing information about the drug supply and, optionally, a unique serial number. Alternatively, the bit code may comprise the unique serial number only, which in that case provides an entry to a table or the like containing further information about the drug supply. The table may be stored in the processing unit.

Providing each supply of drug or inhaler with a unique serial number solves the problem of how to reliably collect information during clinical trials. Clinical trials often involve a large number of patients, each of whom has to fill in a patient's diary one or more times a day during an extended time period. After the test period, the diaries are collected and the data therein is entered in a computer for processing. Unfortunately, the data which is finally processed contains many errors due to incorrectly filled-in diaries and incorrectly entered data.

However, by providing each inhaler used in the clinical trial with means for detecting the dispensation of a dose of drug as well as with a transmitter for transmitting information to a processing unit and by adding the unique serial number to each item of information transmitted to the processing unit, the patients need no longer enter their drug intakes in a patient's diary, but information thereon can be automatically collected and transmitted to the processing unit. Also other data relevant to the clinical trial may be collected and provided with the

unique identity. The processing unit may be part of a computer network, in which data from all patients involved in the clinical trial is processed, or be provided with means for automatically transmitting the data to such a computer network.

The invention will now be described in more detail by way of example and with reference to the accompanying drawings, wherein

Fig. 1 is an exploded view of a powder inhaler which can be used in an inhalation device according to the invention,

Fig. 2 is a block diagram of an electronic unit in the inhaler of Fig. 1, and

Fig. 3 is a block diagram of a processing unit according to the invention.

Fig. 1 shows a powder inhaler which is driven by the patient's own inhalation. The air flow through the inhaler during inhalation is indicated by arrows A.

A rotatable operating unit 1 with a grip ring 2 co-operates with a dosing unit 3 which, when the operating unit 1 is turned, feeds a powder dose to an inhalation channel 4. The active substance is kept in a container 5. A mouthpiece 6 is provided with a deagglomeration means with narrow helical deflection means for deagglomerating the substance powder into an inhalable powder fraction. The dosing unit 3 is shaped as a flat, rotatable disc having groups of dosing holes 8 and being arranged at the bottom of the substance container 5. The dosing holes 8 are filled with substance when positioned below the substance container 5. When the grip ring 2 is turned so as to be indexed one step forward, the dosing disc 3 is entrained in the rotational movement. A number of scrapers 9 engage the dosing disc 3, so that excess powder substance over the dosing holes 8 is removed when turning the dosing disc 3.

When the patient inhales from the mouthpiece opening, air flows through two opposite air inlets 10 in the operating unit 1 and through the group of dosing holes 8 which at the moment is exposed to the inhalation channel 4 situated above the dosing disc 3, through the channel 4 and out through the mouthpiece 6. When the air flow passes the dosing holes 8, the dose of active substance charged in the holes will be released and entrained by the air flow, and finally deagglomerated in the helical passage of the mouthpiece 6.

Inside the mouthpiece 6, between its outer wall and the deagglomeration means 7, an electronic unit 20 is mounted. In Fig. 1, the electronic unit is schematically shown as a block. Fig. 2 is a block diagram of the electronic unit. The electronic unit 20 comprises a differential pressure gauge 21 for measuring the pressure difference between an inlet 11 to the deagglomeration means 7 and an outlet 12 therefrom. Furthermore, the electronic unit 20 comprises a clock circuit 23, a radio transmitter 24, antenna means 25, a power supply 26 and processing circuitry 22 for processing the signals from the differential pressure gauge 21 into a form suitable for transmission by the transmitter. The processing circuitry may comprise a memory for temporary storage of the signals from the pressure gauge before transmission. In addition, the electronic unit 20 comprises electronically readable identification means 27 in the form of a non-volatile memory, which contains a bit code. The bit code may consist of several fields representing, for instance, the kind of drug, the size of dose, the original number of doses in the inhaler, the durability and a unique serial number. In a refillable inhaler, the identification means 27 must be inseparably associated with the package containing the refill drug.

Apart from being utilised for the automatic collection of information during use of the inhaler, the information in the identification means may also be used for

quality control when manufacturing inhalers. For instance, the drug content and the dose size of an inhaler may be checked against the bit code in the identification means by means of a robot, which performs a test inhalation through the inhaler.

The power supply 26 need not be a battery, but may be a chargeable device charged, e.g. inductively, from the processing unit.

The electronic unit 20 is preferably realised as one or more ASICs. The differential pressure gauge 21 is advantageously integrated on one of the ASICs.

The operation of the electronic unit 20 will now be described. When the operating unit 1 of the inhaler is turned to feed a powder dose to the inhalation channel 4, a click sound is produced. This click sound is picked up by the pressure gauge, acting as a microphone or accelerometer.

When the patient inhales through the inhaler, an inhalation air flow passes through the deagglomeration means 7 and a pressure difference is generated between the inlet 11 and the outlet 12 thereof. The pressure difference is measured by the differential pressure gauge 21, and the time of the inhalation is recorded by means of the clock circuit 23. The electric signals produced in response thereto are processed by the processing circuitry 22 into a form suitable for transmission.

The degree of processing of the signals from the pressure gauge is a matter of design. The signals may be transmitted substantially unprocessed or may be subjected to a more thorough processing already in the inhaler, so that only selected information is transmitted. The processing in the inhaler may involve determination of the flow profile of the inhalation flow or parameters thereof. More particularly, since the properties of the helical means of the deagglomeration means 7 are known, the flow profile of the inhalation flow can be determined from the pressure difference measured during inhalation. The flow

profile of the inhalation air flow is of interest by reflecting the pulmonary function of the patient. If the asthma becomes worse, the lung capacity will decrease and the volume of the inhalation air flow diminish. Other interesting parameters of the flow profile affected by the lung function are, for instance, the rise and fall times and the length of the plateau.

The processing of the signals may also involve detection of a dose dispensation. For a valid dose dispensation to be detected, the click sound defining the availability of a dose must be detected as well as an inhalation air flow of a strength sufficient to carry a dose. When a valid dose dispensation is detected, the time thereof is recorded.

The signals from the inhaler can be transmitted continuously during the inhalation or be temporarily stored in the memory and transmitted at a later time. In the former case, the inhaler need not comprise a clock circuit but the time of a dose dispensation may be recorded in the processing unit.

The bit code in the identification means is associated with each item of information being transmitted.

In the embodiment described above, the differential pressure gauge is used both as means for determining a specific feature of the disease being treated with the drug in the inhaler, i.e. the inhalation air flow, and as a detector for detecting the dispensation of a dose. However, other alternatives are conceivable.

For instance, the detection of a dose dispensation and the measuring of the inhalation air flow may be realised by the device according to the above-mentioned EP 387 222. However, this is a less preferred embodiment because a sound signal results in a less accurate measure of the inhalation air flow. In addition, the sound from different inhalers differs considerably and, therefore, individual calibration of each inhaler would probably be necessary. On the contrary, since the properties of the

helical means in the deagglomeration means 7 are similar for all inhalers, no calibration is required if the inhalation air flow is measured there.

Furthermore, the availability of a dose can be detected in other ways than by the click sound, for instance by detecting the mechanical movement of the dosing unit 3.

For inhalers other than the Turbuhaler® inhaler, other means for detecting the availability of a dose and the dispensation thereof may be suitable. Examples are given in EP 387 222.

If the size of the dose is variable, information enabling identification of the size of the individual dose dispensed when the user inhales through the inhaler may be transferred to the processing unit.

Fig. 3 shows a block diagram of a processing unit 30 according to the invention. The processing unit 30 comprises an antenna 31, which is connected to a receiver 32 for receiving information transmitted from one or more inhalers. The receiver is connected to processing circuitry 33 which in turn is connected to a memory 34, a display 35, a key pad 36 and an alarm unit 37, a clock circuit 38, an I/O-unit 39 and a power supply 40. The processing unit may also be provided with a spirometer 41 for measuring the pulmonary function, more precisely as a complement to or as a substitute for the measuring of the inhalation air flow in the inhaler.

The operation of the processing unit 30 will now be described. The receiver 32 receives signals from an inhaler. Each item of information received has associated therewith the bit code of the identification means of the inhaler transmitting the information, so that the processing unit can correctly identify the drug taken and the dose thereof. If the time of an inhalation is recorded by the clock circuit in the inhaler, each item of information will also have associated therewith the time of inhalation.

As mentioned above, the signals may be more or less processed already in the inhaler. Processing not performed in the inhaler is performed in the processing unit by the microprocessor 32. The processed signals are compared with stored signals from earlier measurements. By this comparison, it is possible to detect a change in the patient's state of health, which may necessitate a change of dose or of drugs. Furthermore, the processed signals may be used for determining the effect of an intake of drug and for adapting the time and the size of the next dose with regard to the effect achieved by a previous dose.

The patient can input comments on his state of health or information about conditions which may affect the medication via the key pad 36. The information may be given in the form of answers to questions from the microprocessor 32 displayed on the display 35.

The advice elaborated by the microprocessor 32 on the basis of detected changes in the patient's state of health, the times of intake of different drugs, entered user data and other information stored in the memory 34, is displayed on the display 35. The microprocessor 32 may also activate an audible or visible alarm 37 to draw the user's attention to information displayed on the display 35 or to an action to be taken.

A doctor may communicate with the processing unit by its I/O-unit. He may, for instance, reprogram the processing unit or transfer information stored therein to his personal computer.

Before the processing unit can be used to advise a patient about drugs and doses thereof, data about the specific feature of the disease being treated, i.e. in this case the inhalation air flow, must be collected in the memory 34. The reason for this is that the inhalation air flow of each patient is individual, so that there must be an inhalation air flow history to enable the microprocessor 32 to detect changes in the disease.

It should be pointed out that the processing unit need not be a physically separate unit, but may be integrated in each inhaler.

If the inhaler is used only for collecting data during clinical trials, and not for advising patients, the processing unit to which the collected data is transmitted can be of any type suitable for receiving and processing the data.

The present invention can be used with any kind of inhaler. More particularly, the inhaler may be a multidose breath-activated dry powder inhaler, e.g. a Turbuhaler® inhaler, or a unit dose breath-activated dry powder inhaler for single use, e.g. a Monohaler® inhaler, or a breath-activated dry powder inhaler with a plurality of single-packed unit doses for multiple use, or a pressurised dose inhaler or a metered dose inhaler, or of any other suitable type. Furthermore, it can be used in connection with any kind of disease which is treated by inhalation therapy and of which a specific feature is measurable. For diseases not related to the respiratory passages, the inhalation device necessitates other means for measuring a specific feature of the disease than the means for measuring the inhalation air flows. Such means can be arranged separately from the inhaler and the processing unit, and transmit information by telemetry or on wires to the processing unit.

For instance, the inhalation device may comprise an inhaler for administering nicotine. The means for measuring a specific feature of the disease, i.e. nicotine addiction, could then be a sensor for measuring the nicotine content of the blood, and the processing unit may advise the patient to take such doses of nicotine that the nicotine content of the blood is maintained at a very slowly decreasing level.

Alternatively, the inhalation device may comprise an inhaler for administering peptides and proteins, for example insulin. In the case of insulin, the means for

measuring a specific feature may be a biosensor measuring the glucose level of the blood, and the advice elaborated by the processing unit can assist the patient in maintaining the glucose in the blood at a suitable level.

According to another alternative, the inhaler may comprise a blood pressure regulating drug.

## CLAIMS

1. An inhalation device comprising at least one inhaler for dispensing a dose of a drug to a user inhaling through the inhaler, which contains a supply of the drug and which has means (21-23) for detecting the dispensation of a dose; means (21-23; 38) for measuring a specific feature of the disease being treated with the drug; and a processing unit (30) having storage means (34) for storing this specific feature from a plurality of measurements as well as the time of each detected dispensation of a dose, c h a r a c t e r i s e d by electronically readable identification means (27), which are arranged inseparably from the supply of drug and which contain information enabling the identification of at least the kind of drug in the supply and the size of the dose dispensed when a user inhales through the inhaler; and means for delivering said information to the processing unit.

2. An inhalation device according to claim 1, c h a r a c t e r i s e d in that the inhaler (20) and the processing unit (30) are two physically separate units, the inhaler comprising a transmitter (24) and the processing unit a receiver (32) for enabling transmission of information from the inhaler to the processing unit.

3. An inhalation device according to claim 2, c h a r a c t e r i s e d in that the information is transmitted from the inhaler (20) to the processing unit (30) by radio transmission.

4. An inhalation device according to claim 2, c h a r a c t e r i s e d in that the information is inductively transmitted from the inhaler (20) to the processing unit (30).

5. An inhalation device according to any of the preceding claims, c h a r a c t e r i s e d in that the processing unit (30) comprises analysing means (33) for analysing the stored specific features for detecting

changes in the disease and providing an indication of an action to be taken on the basis of said detected changes and the stored times of dispensation of a dose.

6. An inhaler for dispensing a dose of a drug to a user inhaling through the inhaler, comprising a supply of the drug and means (21-23) for detecting the dispensation of a dose, c h a r a c t e r i s e d by electronically readable identification means (27), which are arranged inseparably from the supply of the drug and which contain information enabling the identification of at least the kind of drug in the supply and the size of the dose dispensed when a user inhales through the inhaler; and a transmitter (24) for transmitting said information to a processing device (30).

7. A device according to any of the preceding claims, c h a r a c t e r i s e d in that the transmitter (24) is adapted to transmit said information in the identification means (27) to the processing unit each time information about a detected dispensation of a dose is transmitted to the processing unit.

8. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the supply of drug is contained in a replaceable package.

9. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the information in the electronically readable identification means (27) further enables the identification of the original number of doses in the supply, and that the device further comprises a counter for counting the doses dispensed from the supply of drug, the counter being mounted inseparably from the supply of drug.

10. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the information in the electronically readable identification means (27) consists of a bit code.

11. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the information in the electronically readable identification means (27) further enables the identification of the durability of the drug.

12. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the electronically readable identification means (27) comprise a non-volatile memory.

13. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the information in the electronically readable identification means (27) consists of a unique serial number.

14. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the inhaler is a breath-actuated dry powder inhaler.

15. A device according to any one of the preceding claims, c h a r a c t e r i s e d in that the inhaler is a Turbohaler®.

FIG.I

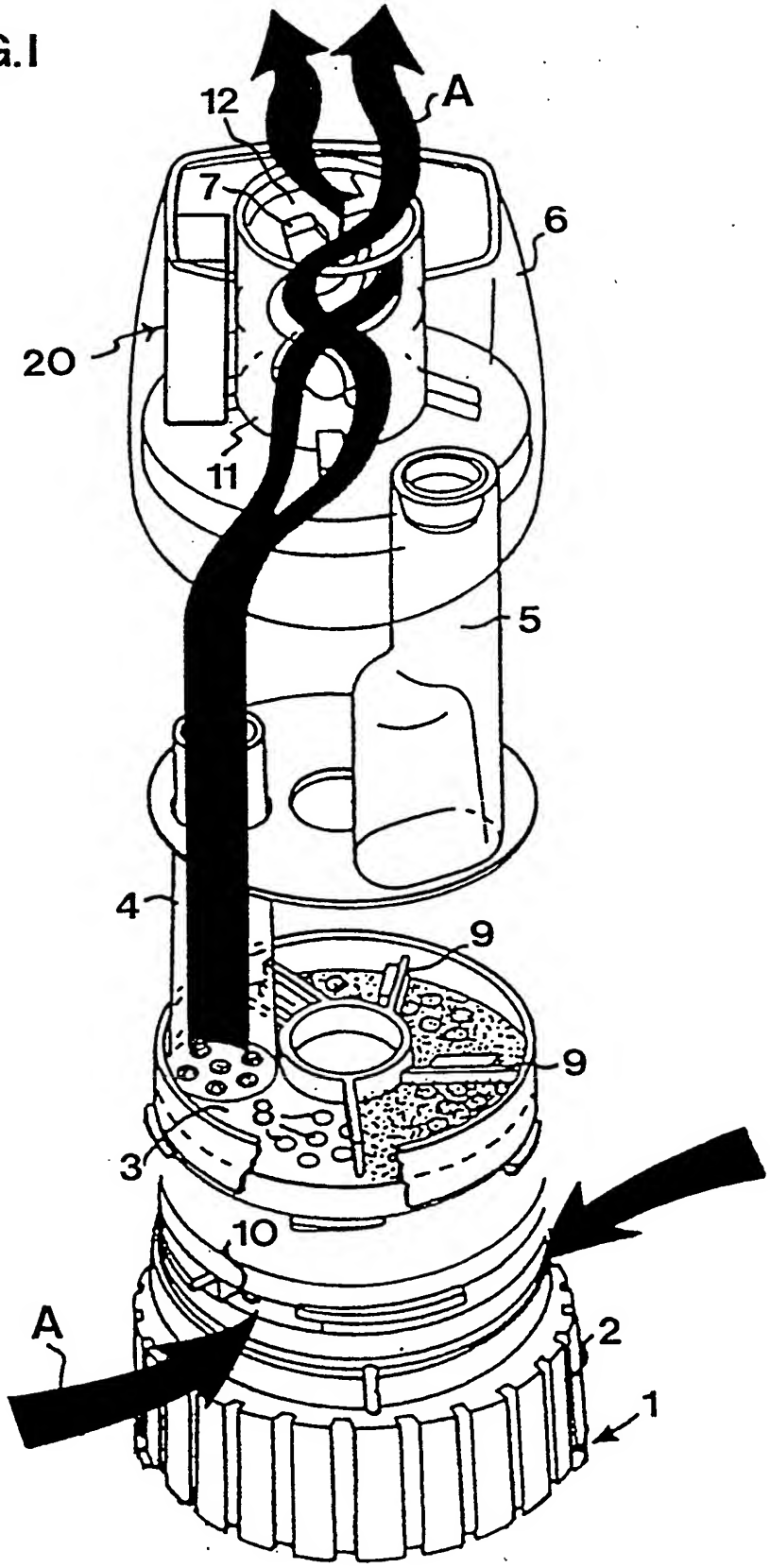


FIG 2

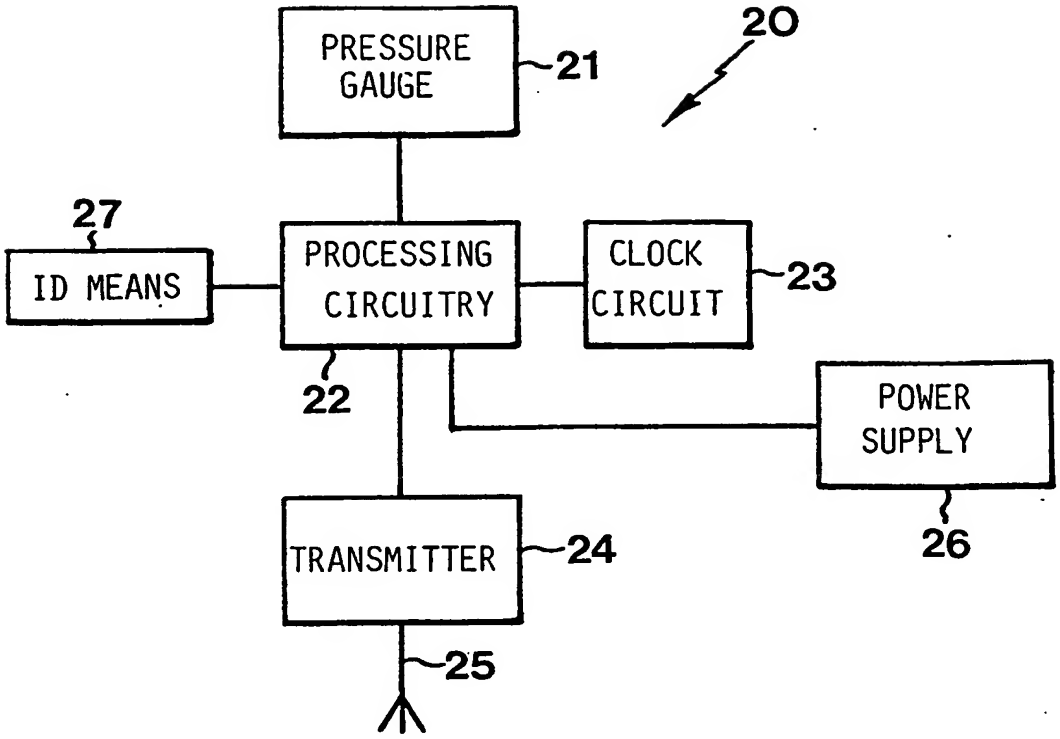
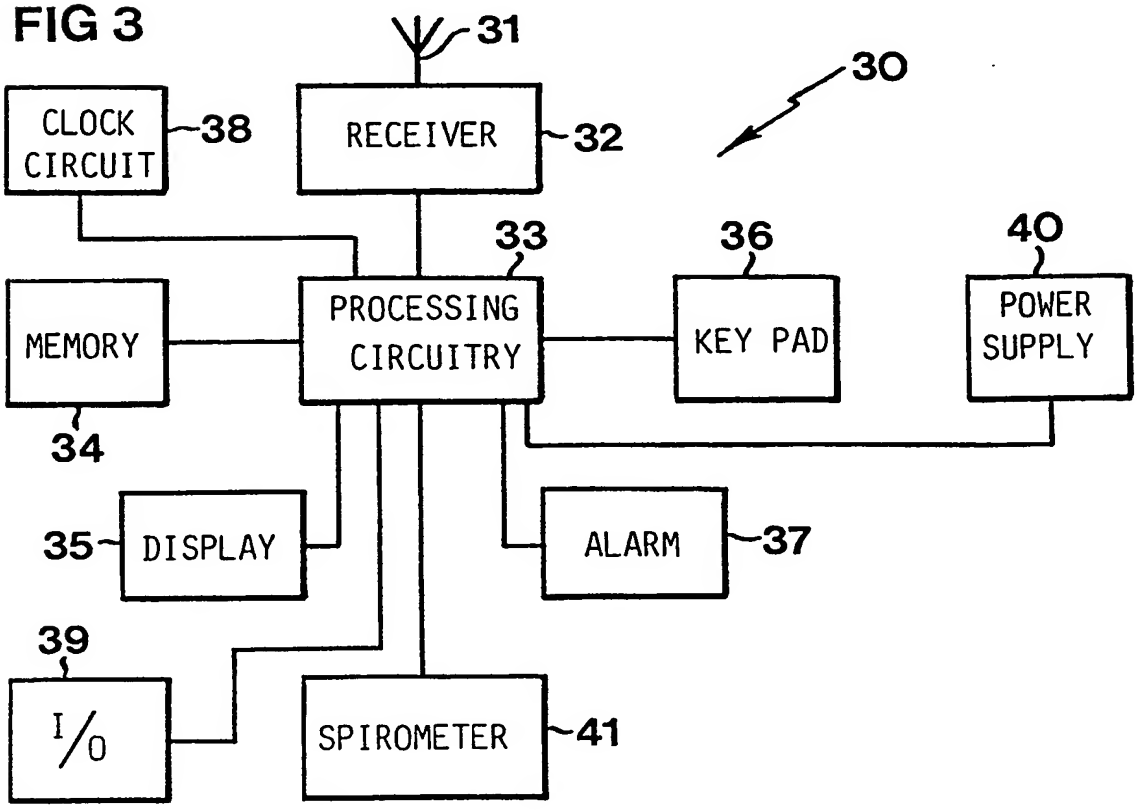

PRESSURE GAUGE
21
20
27
ID MEANS
PROCESSING CIRCUITRY
22
CLOCK CIRCUIT
23
POWER SUPPLY
26
TRANSMITTER
24
25

FIG 3


31
30
CLOCK CIRCUIT
38
RECEIVER
32
33
36
40
MEMORY
PROCESSING CIRCUITRY
KEY PAD
POWER SUPPLY
34
35
DISPLAY
ALARM
37
39
I/O
SPIROMETER
41

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00157

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 15/00
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y1 | WO, A2, 9215353 (MIRIS MEDICAL CORPORATION), 17 Sept 1992 (17.09.92), page 31, line 9 - line 22; page 41, line 1 - line 21 | 1-5 |
| Y2 | WO, A2, 9312823 (AIRWAYS MEDICAL TECHNOLOGIES), 8 July 1993 (08.07.93), page 13, line 3 - line 29; page 19, line 9 - line 34 | 1-5 |

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 June 1995 | 13.06.95 |
| Name and mailing address of the ISA/<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Anette Hall<br>Telephone No. +46 8 782 25 00 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/00157

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y1 | WO, A1, 9217231 (INNOMED, INC), 15 October 1992 (15.10.92), page 6, line 5 - line 32; page 10, line 13 - line 21; page 11, line 29 - line 34 | 1-5 |
| Y2 | | 1-5 |
| X | | 6-15 |

--

---

# INTERNATIONAL SEARCH REPORT

Information on patent family members

03/05/95

International application No.
PCT/SE 95/00157

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO-A2- 9215353 | 17/09/92 | EP-A,A- 0529053 | 03/03/93 |
| | | US-A- 5392768 | 28/02/95 |
| | | US-A- 5394866 | 07/03/95 |
| | | US-A- 5404871 | 11/04/95 |
| WO-A2- 9312823 | 08/07/93 | CA-A- 2126331 | 08/07/93 |
| | | EP-A,A- 0617628 | 05/10/94 |
| | | US-A- 5363842 | 15/11/94 |
| WO-A1- 9217231 | 15/10/92 | NONE | |